510(k) Summary
[As required by 21 CFR 807.92(c)]

JUN 1 4 2013

1. Submitter's Name / Contact Person

Submitter:	TriReme Medical, Inc. 7060 Koll Center Parkway, Suite 300 Pleasanton, CA 94566
Contact Person:	Shiva Ardakani VP of RA/QA/CA Phone: 925-931-1300 Ext 209 Fax: 925-931-1361
Date Prepared:	February 14, 2013

2. General Information

Trade Name:	Chocolate PTA Balloon Catheter
Common/Usual Name:	Angioplasty Catheter
Classification Name:	Percutaneous Catheter (21 CFR 870.1250)
Product Code:	LIT
510(k) number:	
Predicate Devices:	B. Braun Mini Ghost (K051343) Chocolate PTA Balloon Catheter Family (K111738, K120677, K121402 and K122070)

3. Intended Use

The Chocolate PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. NOT for use in the coronary or cerebral vasculature.

4. Device Description

The Chocolate PTA Balloon Catheter is a standard balloon dilatation catheter with a braided shaft and an atraumatic, tapered and beveled tip. The device is compatible with commonly used accessories, including standard 0.014" and 0.018" guidewires and 5F introducer sheath (or 6F guide catheter). Overall catheter lengths are approximately 120 cm to 150cm.

All materials are identical to approved PTA Balloon Catheter family of products. The distal end of the catheter has a semi-compliant balloon that expands to known diameters (refer to compliance chart) at specific pressures. The balloon contains radiopaque markers to assist with positioning. The Constraining Structure (CS) has been added to the distal part of the catheter. The shaft is braid reinforced and the hydrophilic coating of the braided shaft will become optional. The proximal end of the device is a common PTA

catheter connected to a plastic hub and strain relief. The hub is used to inflate the balloon; the luer connector is compatible with standard inflation devices.

The Chocolate Balloon Catheters are supplied sterile and intended for single use only.

5. Performance Data

Bench testing was performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
The following *in vitro* tests were performed:

- Peak friction force in a established peripheral model

6. Substantial Equivalence Comparison and Conclusion

The Chocolate PTA Balloon Catheter without hydrophilic coating on the distal portion of the braided shaft is substantially equivalent to the predicate devices in design, materials, packaging, fundamental scientific technology, manufacturing, sterilization and intended use. Performance testing demonstrated that the devices reliably achieved the desired effect and are safe for the intended use. No new questions of safety or effectiveness were identified during device testing. Therefore, Chocolate PTA Balloon Catheters with the hydrophilic coating removed are considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 15, 2013

TriReme Medical, Inc.
Ms. Shiva Ardakani
VP of Regulatory, Clinical and Quality
7060 Koll Center Parkway, Suite 300
Pleasanton, CA 94566

Re: K130414
Trade/Device Name: Chocolate PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: LIT
Dated: April 26, 2013
Received: April 29, 2013

Dear Ms. Ardakani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (XXXXX):

Device Name: Chocolate PTA Balloon Catheter

Indications for Use:

The Chocolate PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. NOT for use in the coronary or cerebral vasculature.

The indication for use is the same for all members of the Chocolate PTA Balloon Catheter Family.

Prescription Use — X — (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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